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10/682,460	10/08/2003	Kenneth E. Kadziauskas	27564	1644

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EXAMINER	
HAND, MELANIE JO	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	**Application No.** 10/682,460	**Applicant(s)** KADZIAUSKAS ET AL.
	Examiner MELANIE J. HAND	**Art Unit** 3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 February 2010*.
2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,23,24,29-40 and 46-52* is/are pending in the application.
4a) Of the above claim(s) *6,8,12,13,34,36 and 40* is/are withdrawn from consideration.
5)☒ Claim(s) *23,24,47 and 52* is/are allowed.
6)☒ Claim(s) *1-5,7-9,12-14,29-33,35,37,46 and 48-51* is/are rejected.
7)☒ Claim(s) *10,11,38 and 39* is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a)☐ All b)☐ Some * c)☐ None of:
1.☐ Certified copies of the priority documents have been received.
2.☐ Certified copies of the priority documents have been received in Application No. _____.
3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 15, 2010 has been entered.

Response to Arguments

2. Applicant's arguments filed February 15, 2010 with respect to claims 1-5, 7-9, 12-14, 29-33, 35 and 37 have been fully considered but they are not persuasive. Applicant argues that Saravia does not disclose or suggest an irrigation line comprising an output port and a tubular member comprising an input port attached to the output port as recited in claims 1 and 29. The recited input and output ports are only supported in applicant's specification insofar as the irrigation line has an outlet opening and the tubular member has an inlet opening wherein the irrigation line end is inserted into the tubular member input opening. Thus, that is the manner in which the terms "input port" and "output port" are interpreted by the examiner. As Saravia also discloses such an arrangement, i.e. a tubing line for irrigation having one end inserted into an inlet end of the accumulator, Saravia does in fact disclose input and output ports as claimed. Therefore the rejections of these claims are maintained.

3. It is noted that applicant states that new claim 46 contains all of the limitations of claims 1, 5, 7 and 9 and thus is in condition for allowance. Applicant is reminded that it is claims 10, 11,

38 and 39 that are drawn to allowable subject matter. These claims whose limitations are included in the new claims are still rejected. Thus claim 46 is also rejected.

Specification

4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: there is no antecedent basis for the following:.(1) the output port of the irrigation line, (2) the input port of the tubular member and (3) the output port of the tubular member.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 49 and 51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no support in the disclosure as originally filed for the limitation "some fluid from said fluid supply flows through said tubular member but does not flow through said section." In order to reach the tubular member, all fluid from the fluid supply must flow through the section of the irrigation line that extends between the input and output ports of the tubular member.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 1 recites the limitation "said output port of said tubular member" in line 7. There is insufficient antecedent basis for this limitation in the claim. The claim only recites an output port of the recited irrigation line, not the tubular member. Claims 2-5, 7, 9-11, 14 and 48 depend directly or ultimately from claim 1 and are thus also rejected.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1, 3, 4, 48 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saravia (U.S. Patent No. 6,106,494).

With respect to **claim 1:** Saravia discloses an infusion source for an ocular surgery in the form of fluid management system 20 comprising a fluid supply in the form of supply bags (not shown), an irrigation line in the form of inflow tube 28 interconnecting said fluid supply bags and an irrigation lumen in the form of first low-loss cannula 30, said irrigation line comprising an outlet port; and a tubular member in the form of accumulator 29 separate from, and in a parallel fluid relationship with, said irrigation line and comprising an input port attached to both an output port of the tubular member and an output port of the irrigation line. The tubular member 29 has an expandable wall configured to expand during occlusion of the irrigation lumen 30 during pressure buildup at the surgical site. The recited input and output ports are only supported in applicant's specification insofar as the irrigation line has an outlet opening and the tubular member has an inlet opening wherein the irrigation line end is inserted into the tubular member input opening. Thus, that is the manner in which the terms "input port" and "output port" are interpreted by the examiner. As Saravia also discloses such an arrangement, i.e. a tubing line for irrigation having one end inserted into an inlet end of the accumulator, Saravia discloses input and output ports as claimed.

Saravia discloses that the tubular member 29 is separate from the irrigation line 28, but discloses that it is in serial fluid relationship with the line, rather than in a parallel fluid relationship with said irrigation line 28. However Saravia discloses that the accumulator 29 remedies drastic increases in pressure in a surgical site (e.g. the joint capsule of the knee), and the accumulator prevents backflow of fluid from the site. Since this backflow can also cause contamination of the draining line, and such an accumulator would be equally capable of preventing backflow of suction, it would be obvious to one of ordinary skill in the art to modify the system of Saravia such that an additional accumulator placed in the draining outflow line 34 is separate from, and in parallel fluid communication with, the irrigation line 28, to prevent backflow or drainage pressure buildup. The expandable wall of the accumulator in the outflow aspiration line 34 suggested by Saravia is configured to expand during occlusion of an aspiration lumen 32 due to pressure buildup at a surgical site disclosed by Saravia.

With respect to **claim 3:** The tubular member 29 is disposed in serial fluid communication with said irrigation line 28 and irrigation lumen 30.

With respect to **claim 4:** The tubular member wall 198 is formed from an elastic material, namely an elastic balloon.

With respect to **claim 48:** The tubular member disclosed by Saravia comprises an output port in fluid communication with said irrigation line inasmuch as a portion of the irrigation line tubing is in communication with a opening of the tubular member through which accumulated fluid is released.

With respect to **claim 49:** A section of said irrigation line 28 disclosed by Saravia is disposed between said input and output ports 199,200 of said tubular member 29, wherein some fluid from said fluid supply flows through said tubular member to cause the balloon to expand and fill the expanded portions, but does not flow through said section in order to prevent excessive pressure buildup and backflow. Some fluid from said fluid supply flows through said section but does not flow through said tubular member when there is no blockage or backflow scenario in the irrigation line.

12. Claims 2 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saravia (‘494) in view of Urich (U.S. Patent No. 7,083,591).

With respect to **claim 2:** The tubular member 29 disclosed by Saravia is disposed proximate a handpiece, defined collectively by hand controller 38 by either the grippable portion of cannula 30 or the grippable portion of cannula 32. The handpiece disclosed by Saravia is not effective for use in a phacoemulsification procedure. Urich discloses a tubular member proximate a handpiece in the form of surgical instrument 11 effective for use in a phacoemulsification procedure inasmuch as the handpiece 11 has an ultrasonic vibrating tip 12 that is inserted into the cornea, which is the device used in a phacoemulsification procedure. (‘448, Col. 1, lines 10-14, Col. 4, lines 43-45) The devices of Saravia and Urich seek to solve a similar problem in the art, i.e. providing a hand controllable and manipulable means for delivering fluid and suction to a surgical site. Thus, it would be obvious to one of ordinary skill in the art to modify the infusion source disclosed by Saravia by replacing the hand controller and cannulas with the handpiece disclosed by Urich with a reasonable expectation of success to allow use of the system in ocular surgery.

With respect to **claim 14:** The infusion source disclosed by Saravia comprises a handpiece, however the handpiece that comprises a cannula with said irrigation lumen 30. However the cannula is not a needle. Urich teaches an infusion source comprising: a surgical instrument 11 considered herein to be a handpiece inasmuch as Urich teaches that the instrument 11 has a tip 12 for insertion into the cornea for use in a known emulsification procedure that cannot be accomplished with a non-handheld device. The handpiece 11 has a needle in the form of sleeve 14 with sharp tip 12 positioned therein at an end of said sleeve 14 with an irrigation lumen defined by the inner wall of sleeve 14 (Col. 2, lines 14-23) The devices of Saravia and Urich seek to solve a similar problem in the art, i.e. providing a hand controllable and manipulable means for delivering fluid and suction to a surgical site via an irrigation lumen in the form of a cannula. Thus, it would be obvious to one of ordinary skill in the art to modify the infusion source disclosed by Saravia by replacing the hand controller and cannula with the handpiece disclosed by Urich having a needle with a reasonable expectation of success to allow use of the system in ocular surgery.

13. Claims 5, 7 and 9 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saravia (‘494) in view of Rehn et al (JP 2000-120602 A) (English translation).

With respect to **claim 5:** Saravia does not disclose that the tubular member 29 comprises a sheath disposed around the expandable wall. Rehn discloses a pressure accumulator comprising a tubular member in the form of hose-like diaphragm 10 having a sheath in the form of cover part 12 disposed around the expandable wall of tubular member 10. Rehn discloses that the sheath 12 prevents inconvenient expansion of tubular member 10. (‘602, ¶0021) Therefore, it would be obvious to one of ordinary skill in the art to modify the tubular member disclosed by Saravia so as to comprise a sheath disposed around the tubular member as disclosed by Rehn to prevent inconvenient expansion of the tubular member which can prevent the intended control of fluid pressure by the tubular member.

With respect to **claim 7:** Saravia does not disclose that the tubular member 29 comprises a sheath disposed around the expandable wall. The sheath 12 disclosed by Rehn is flexible. (‘602, ¶0021) The motivation to modify the infusion source of Saravia such that the tubular member comprises a sheath disposed around said expandable wall is stated *supra* with respect to claim 5.

With respect to **claim 9:** Saravia does not disclose a sheath and therefore does not disclose that the sheath and expandable wall are integrally molded. Rehn discloses a tubular member comprising a sheath, and discloses that the sheath and tubular member 10 are unified, but does not explicitly disclose that the sheath and the expandable wall are integrally molded. It is examiner's position that an expandable wall and sheath that are unified by being integrally molded will yield an accumulator that is structurally and functionally identical to the article explicitly disclosed by Rehn. Therefore it would be obvious to one of ordinary skill in the art to modify the unified expandable wall of the tubular member and sheath such that they are unified by being integrally molded with a reasonable expectation of success to provide an accumulator that functions as intended, preventing inconvenient expansion of the tubular member. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113.* The burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. See also *In re Marosi,* 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983)

With respect to **claim 46:** Saravia discloses an infusion source for an ocular surgery in the form of fluid management system 20 comprising a fluid supply in the form of supply bags (not shown), an irrigation line in the form of inflow tube 28 interconnecting said fluid supply bags and an irrigation lumen in the form of first low-loss cannula 30, said irrigation line comprising an outlet port; and a tubular member in the form of accumulator 29 separate from, and in a parallel fluid relationship with, said irrigation line and comprising an input port attached to both an output port of the tubular member and an output port of the irrigation line. The tubular member 29 has an expandable wall configured to expand during occlusion of the irrigation lumen 30 during pressure buildup at the surgical site. The recited input and output ports are only supported in applicant's specification insofar as the irrigation line has an outlet opening and the tubular member has an inlet opening wherein the irrigation line end is inserted into the tubular member input opening. Thus, that is the manner in which the terms "input port" and "output port" are interpreted by the examiner. As Saravia also discloses such an arrangement, i.e. a tubing line for irrigation having one end inserted into an inlet end of the accumulator, Saravia discloses input and output ports as claimed.

Saravia discloses that the tubular member 29 is separate from the irrigation line 28, but discloses that it is in serial fluid relationship with the line, rather than in a parallel fluid relationship with said irrigation line 28. However Saravia discloses that the accumulator 29 remedies drastic increases in pressure in a surgical site (e.g. the joint capsule of the knee), and the accumulator prevents backflow of fluid from the site. Since this backflow can also cause contamination of the draining line, and such an accumulator would be equally capable of preventing backflow of suction, it would be obvious to one of ordinary skill in the art to modify the system of Saravia such that an additional accumulator placed in the draining outflow line 34 is separate from, and in parallel fluid communication with, the irrigation line 28, to prevent backflow or drainage pressure buildup. The expandable wall of the accumulator in the outflow aspiration line 34 suggested by Saravia is configured to expand during occlusion of an aspiration lumen 32 due to pressure buildup at a surgical site disclosed by Saravia.

Saravia does not disclose that the tubular member 29 comprises a sheath disposed around the expandable wall. Rehn discloses a pressure accumulator comprising a tubular member in the form of hose-like diaphragm 10 having a sheath in the form of cover part 12 disposed around the expandable wall of tubular member 10. Rehn discloses that the sheath 12 prevents inconvenient expansion of tubular member 10. (‘602, ¶0021) Therefore, it would be obvious to one of ordinary skill in the art to modify the tubular member disclosed by Saravia so as to comprise a sheath disposed around the tubular member as disclosed by Rehn to prevent inconvenient expansion of the tubular member which can prevent the intended control of fluid pressure by the tubular member.

Saravia does not disclose that the tubular member 29 comprises a sheath disposed around the expandable wall. The sheath 12 disclosed by Rehn is flexible. (‘602, ¶0021)

Saravia does not disclose a sheath and therefore does not disclose that the sheath and expandable wall are integrally molded. Rehn discloses a tubular member comprising a sheath, and discloses that the sheath and tubular member 10 are unified, but does not explicitly disclose that the sheath and the expandable wall are integrally molded. It is examiner's position that an expandable wall and sheath that are unified by being integrally molded will yield an accumulator that is structurally and functionally identical to the article explicitly disclosed by Rehn. Therefore it would be obvious to one of ordinary skill in the art to modify the unified expandable wall of the tubular member and sheath such that they are unified by being integrally molded with a reasonable expectation of success to provide an accumulator that functions as intended, preventing inconvenient expansion of the tubular member. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe, 777 F.2d 695, 227 USPQ 964*

(Fed. Cir. 1985). See also MPEP § 2113. The burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. See also *In re Marosi,* 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983)

14. Claims 29-32, 50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saravia (‘494) in view of Sepielli (U.S. Patent No. 5,554,894).

With respect to **claim 29:** Saravia discloses a surgical system for performing surgery comprising a handpiece connected to cannulas 30 and 32 for delivering and draining fluid through cannulas 30 and 32, respectively, driven by a controller in the form of hand controller 38. The system also comprises an irrigation lumen defined by cannula 30, a fluid supply in the form of supply bags (not shown), an irrigation line in the form of inflow tube 28 interconnecting said fluid supply and said irrigation lumen 30. The system comprises a tubular member in the form of accumulator 29 separate from said irrigation line 28 and in fluid communication with said irrigation line 28 and said irrigation lumen 30. The tubular member 29 has an expandable wall defined by balloon 198 configured to expand-during occlusion of the irrigation lumen 30 due to pressure buildup from a surgical site. The recited input and output ports are only supported in applicant's specification insofar as the irrigation line has an outlet opening and the tubular member has an inlet opening wherein the irrigation line end is inserted into the tubular member input opening. Thus, that is the manner in which the terms "input port" and "output port" are interpreted by the examiner. As Saravia also discloses such an arrangement, i.e. a tubing line for irrigation having one end inserted into an inlet end of the accumulator, Saravia discloses input and output ports as claimed.

Saravia discloses that the tubular member 29 is separate from the irrigation line 28, but discloses that it is in serial fluid relationship with the line, rather than in a parallel fluid relationship with said irrigation line 28. However Saravia discloses that the accumulator 29 remedies drastic increases in pressure in a surgical site (e.g. the joint capsule of the knee), and the accumulator prevents backflow of fluid from the site. Since this backflow can also cause contamination of the draining line, and such an accumulator would be equally capable of preventing backflow of suction, it would be obvious to one of ordinary skill in the art to modify the system of Saravia such that an additional accumulator placed in the draining outflow line 34 is separate from, and in parallel fluid communication with, the irrigation line 28, to prevent backflow or drainage pressure buildup. The expandable wall of the accumulator in the outflow asipration line 34 suggested by Saravia is configured to expand during occlusion of an aspiration lumen 32 due to pressure buildup at a surgical site disclosed by Saravia.

Saravia does not disclose that the handpiece is driven by a controller through a power line. Sepielli teaches a footswitch 101 for controlling a surgical phacoemulsification handpiece for ophthalmic surgery that is connected to said handpiece via a power line in the form of cable 115 having connector 123. (Col. 4, lines 15-19) Sepielli teaches that the footswitch supplies power to the handpiece remotely and allows the surgeon to adjust the power settings or preset patterns remotely via switches 105,107,109,111 and a touch-screen display 133, therefore it would be obvious to one of ordinary skill in the art to modify the device of Saravia such that said handpiece driven by a controller is driven through a power line as taught by Sepielli to provide a means for remotely powering and controlling the handpiece to prevent unnecessary interruption of surgery for adjustment. (‘894, Col. 3, lines 28-38)

With regard to the limitation “an ocular surgical system for performing ocular surgery on an eye” since the system of Saravia as modified by Sepielli meets all of the limitations of claim 29, the system of Saravia as modified by Sepielli renders this limitation obvious.

With respect to **claim 30:** The tubular member 29 disclosed by Saravia is disposed proximate the handpiece 38,30,32.

With respect to **claim 31:** The tubular member 29 disclosed by Saravia is disposed in serial fluid communication with said irrigation line 28 and irrigation lumen 30.

With respect to **claim 32:** The tubular member wall disclosed by Saravia is formed from an elastic material, namely an elastic balloon 198.

With respect to **claim 50:** The tubular member disclosed by Saravia comprises an output port in fluid communication with said irrigation line inasmuch as a portion of the irrigation line tubing is in communication with a opening of the tubular member through which accumulated fluid is released.

With respect to **claim 51:** A section of said irrigation line 28 disclosed by Saravia is disposed between said input and output ports 199,200 of said tubular member 29, wherein some fluid from said fluid supply flows through said tubular member to cause the balloon to expand and fill the expanded portions, but does not flow through said section in order to prevent excessive pressure buildup and backflow. Some fluid from said fluid supply flows through said section but does not flow through said tubular member when there is no blockage or backflow scenario in the irrigation line.

15. Claims 33, 35 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saravia (‘494) in view of Sepielli (U.S. Patent No. 5,554,894) as applied to claim 29 above, and further in view of Rehn et al (JP 2000-120602 A) (English translation).

With respect to **claim 33:** Saravia does not disclose that the tubular member 29 comprises a sheath disposed around the expandable wall. Rehn discloses a pressure accumulator comprising a tubular member in the form of hose-like diaphragm 10 having a sheath in the form of cover part 12 disposed around the expandable wall of tubular member 10. Rehn discloses that the sheath 12 prevents inconvenient expansion of tubular member 10. (‘602, ¶0021) Therefore, it would be obvious to one of ordinary skill in the art to modify the tubular member disclosed by Saravia so as to comprise a sheath disposed around the tubular member as disclosed by Rehn to prevent inconvenient expansion of the tubular member which can prevent the intended control of fluid pressure by the tubular member.

With respect to **claim 35:** Saravia does not disclose that the tubular member 29 comprises a sheath disposed around the expandable wall. The sheath 12 disclosed by Rehn is flexible. (‘602, ¶0021) The motivation to modify the infusion source of Saravia such that the tubular member comprises a sheath disposed around said expandable wall is stated *supra* with respect to claim 33.

With respect to **claim 37:** Saravia does not disclose a sheath and therefore does not disclose that the sheath and expandable wall are integrally molded. Rehn discloses a tubular member comprising a sheath, and discloses that the sheath and tubular member 10 are unified, but does not explicitly disclose that the sheath and the expandable wall are integrally molded. It is examiner's position that an expandable wall and sheath that are unified by being integrally molded will yield an accumulator that is structurally and functionally identical to the article explicitly disclosed by Rehn. Therefore it would be obvious to one of ordinary skill in the art to modify the unified expandable wall of the tubular member and sheath such that they are unified by being integrally molded with a reasonable expectation of success to provide an accumulator that functions as intended, preventing inconvenient expansion of the tubular member. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113.* The burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. See also *In re Marosi,* 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983)

Allowable Subject Matter

1. Claims 23, 24, 47 and 52 are allowed.
2. Claims 10, 11, 38 and 39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Reasons for Indicating Allowable Subject Matter

3. The statement of reasons for the indication of allowable subject matter with regard to claims 10, 11, 38 and 39 is found in the non-final action mailed November 12, 2008. As applicant neither amended those claims to overcome the objection nor presented persuasive arguments overcoming the rejection of the base claims 1 and 29, the objection is maintained.

Reasons for Allowance

4. The following is an examiner's statement of reasons for allowance:

a. Applicant amended claim 23 to be in independent form to include all of the limitations of the base claim (claim 45, now cancelled) and all intervening claims. Claim 24 depends from claim 23.

b. With respect to new claim 47, since Saravia does not disclose or suggest that the tubular member has a sheath, one of ordinary skill in the art would not be motivated to first modify the system such that the tubular member has a sheath and then further modify the resulting system such that the sheath is flexible and integrally molded to the expandable wall of the tubular member.

c. With respect to new claim 52, Saravia does not disclose or suggest an irrigation line including a segment in parallel fluid relationship with said tubular member. While Saravia fairly suggests a fluid accumulator/tubular member in parallel relationship with the irrigation line, one of ordinary skill in the art would not be motivated to first modify the system such that the irrigation line is in parallel relationship with the tubular member, especially when Saravia discloses that the tubular member is in series with the irrigation line, and then modify the resulting system such that the parallel relationship is effected by adding a segment in the irrigation line in parallel relationship with said irrigation line that contains the tubular member.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled “Comments on Statement of Reasons for Allowance.”

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/

Primary Examiner, Art Unit 3761